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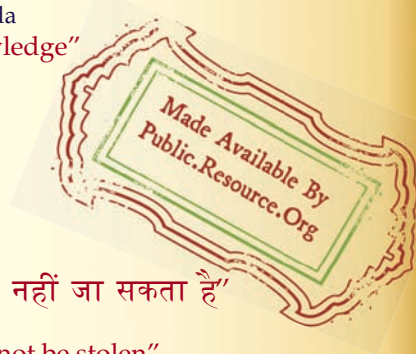
IS 1108 (1975): Pharmaceutical Glass Containers [MHD 10: Medical Laboratory Instruments]



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*‘Indian Standard*  
SPECIFICATION FOR  
PHARMACEUTICAL GLASS CONTAINERS  
*( Second Revision )*

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**Third Reprint AUGUST 1997**

**UDC 615.014.83:666.17**

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**BUREAU OF INDIAN STANDARDS**  
MANAK BHAVAN, 9 BAHADUR SHAH ZAFAR MARG  
NEW DELHI 110002

# Indian Standard

## SPECIFICATION FOR PHARMACEUTICAL GLASS CONTAINERS

### ( Second Revision )

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# ***Indian Standard***

## SPECIFICATION FOR PHARMACEUTICAL GLASS CONTAINERS

### **( *Second Revision* )**

#### 0. FOREWORD

0.1 This Indian Standard (Second Revision) was adopted by the Indian Standards Institution on 31 December 1975, after the draft finalized by the Glass Containers Sectional Committee had been approved by the Marine, Cargo Movement and Packaging Division Council.

0.2 This standard was first published in 1957 and subsequently revised in 1965. The present version brings the standard up-to-date. Provision is made for different types of closures and neck finishes.

0.3 For the purpose of deciding whether a particular requirement of this standard is complied with, the final value, observed or calculated, expressing the result of a test or analysis, shall be rounded off in accordance with IS : 2-1960\*. The number of significant places retained in the rounded off value should be **the same** as that of the specified value in this standard.

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#### 1. SCOPE

**1.1** This standard prescribes the requirements, the methods of **sampling** and test for pharmaceutical glass containers.

#### 2. TERMINOLOGY

**2.1** For the purposes of this standard, the definitions given in IS: 1382-1961† and IS: 6654-1972‡ shall apply.

#### 3. TYPES

**3.1** The pharmaceutical glass containers shall be one of the **following** types depending on their neck finish:

- a) Stoppered,
- b) Roll-on screw non-pilfer proof (RSNP),
- c) Roll-on screw pilfer-proof (RSPP),

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\*Rules for rounding off numerical values ( *revised* ).

†Glossary of terms relating to glass industry.

‡Glossary of glass packaging terms.

- d) Crown cork,
- e) Goldie seal,
- f) Snap-on,
- g) Plug type,
- h) Plastic closure screw thread, and
- j) Cap to cap

#### **4. REQUIREMENTS**

**4.1 Pattern** — The containers shall be round, oval or flat.

**4.2 Material and Workmanship** — The containers shall be made of clear or amber coloured glass, and have a smooth surface without cracks, pinholes or sharp edges. They shall be free from cords, blisters and stones and, as far as possible, free from loading marks.

**4.2.1** The containers shall be well formed with a uniform distribution of glass all over the walls and the base, avoiding any wedge bottom.

**4.2.2 Annealing-** The bottles shall be well annealed and shall not contain strains more than that shown by standard strain disc No. 4.

#### **4.3 Construction and Finish**

**4.3.1** The containers shall be regular in shape and smoothly finished and, when placed on a horizontal plane, shall rest evenly.

**4.3.2 Neck Finish** — The different finishes shall be as follows.

**4.3.2.1 Stoppered containers** — For stoppered container, the interior of the neck shall be smoothly ground to suit the stopper and shall have minimum taper of one in ten. The outer surface of the plug shall also be smoothly ground and shall be well fitting into the mouth of the glass container.

**4.3.2.2 Screw thread** — For screw threaded containers, the external screw threads shall be in accordance with IS : 5851-1970\*. Roll-on seal pilfer-proof ( RSPP ) and roll-on seal non-pilfer-proof ( RSNP ) neck finishes shall be in accordance with Tables 3 and 4 respectively of IS : 751 1-1974†. RSPP finish shall correspond to the standard finish.

**4.3.2.3 Crown cork** — For the crown corked containers, the neck finish shall be in accordance with Table 5 of IS : 751 1-1974†.

**4.3.2.4 Goldie seal** — For the goldie seal type containers the neck finish shall be in accordance with Table 6 of IS : 751 1-1974†.

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\*Finishes with external screw thread for glass containers and gauger for inspection of screw closures.

†Summary sheet on glass container neck finishes.



**4.3.2.5 Snug-on, plug type, plastic colosure screw thread and cap to cap** — For these neck finishes the finish dimensions shall be mutually agreed to between the packer, cap manufacturer and glass container manufacturer.

**4.3.3 Leak-proofness** — The closure containers shall not show any sign of leakage through closures, when the bottle half filled with a 0.5 percent (v/v) aqueous solution of a non-ionic surface active agent is kept inverted for 2 minutes with the closure securely held in position.

#### 4.4 Capacity

**4.4.1'** The nominal capacities of the container shall be:

5, 10, 15, 30, 50, 100, 115, 200, 250, 450, 500, and 1 000 ml.

**4.4.2** The corresponding brimful capacities and the tolerances shall be as given in Table 1.

**4.5 Dimensions** -The pharmaceutical containers with RSNP and RSPP neck finishes shall conform to the dimensions given in Table 2.

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TABLE 1 CAPACITIES AND TOLERANCES OF PHARMACEUTICAL GLASS CONTAINERS  
( Clause 4.4.2 )

NOMINAL CAPACITY	BRIMFUL CAPACITY	TOLERANCE ON BRIMFUL CAPACITY
(1)	(2)	(3)
ml	ml	ml
5	10.0	± 1
10	15.5	± 1
15	19	± 2
30	38	± 3
50	60	± 3
100	115	± 5
115	135	± 6
200	225	± 8
250	280	± 8
450	480	± 10
500	530	± 10
1 000	1060	± 15

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**TABLE 2 DIMENSIONS FOR PHARMACEUTICAL GLASS CONTAINERS  
WITH RSNP AND RSPP NECK FINISHES**

NOMINAL CAPACITY	OVERALL HEIGHT	NECK FINISH	*APERTURE	MINIMUM BORE
(1)	(2)	(3)	(4)	(5)
ml	mm	mm	mm	mm
5	51.0 ± 1.0	22	12.0 ± 0.5	10
10	58.0 ± 1.0	22	12.0 ± 0.5	10
15	64.0 ± 1.0	22	12.0 ± 0.5	10
30	84.0 ± 1.0	22	12.0 ± 0.5	10
50	100.0 ± 1.0	22	12.0 ± 0.5	10
100	115.0 ± 1.0	25	16.0 ± 0.5	13.5
		28	19.0 ± 0.5	16.5
115	125.5 ± 1.0	25	16.0 ± 0.5	13.5
		28	19.0 ± 0.5	16.5
200	150.0 ± 1.0	25	16.0 ± 0.5	13.5
		28	19.0 ± 0.5	16.5
250	155.0 ± 1.0	25	16.0 ± 0.5	13.5
		28	19.0 ± 0.5	16.5
450	192.0 ± 1.0	25	16.0 ± 0.5	13.5
		28	19.0 ± 0.5	16.5
500	187.0 ± 1.0	25	16.0 ± 0.5	13.5
		28	19.0 ± 0.5	16.5
1 000	225.0 ± 1.0	28	19.0 ± 0.5	16.5
		31.5	22.0 ± 0.5	19.5

\*Recommendatory aperture.

**4.6 Limit of Alkalinity**—When tested and graded according to the method prescribed in 3.0 of IS:2303-1963\*, the glass shall conform to Type 4.

**4.7 Thermal Shock Test** — Only round glass containers shall pass the thermal shock resistance test when tested by Method A in accordance with IS :6506-1972†.

## 5. PACKING AND MARKING

5.1 The containers shall be packed as agreed to between the purchaser and the supplier.

\*Method of grading glass for alkalinity.

†Method for thermal shock tests on glassware.

5.2 Each container, except in case of tubular glass containers, shall be permanently and legibly marked on its bottom with the manufacturer's name or registered trade-mark, if any.

### **5.3 BIS Certification Marking**

**The product may also be marked with Standard Mark.**

**5.3.1 The use of the Standard Mark is governed by the provisions of the Bureau of Indian Standards Act, 1986 and the Rules and Regulations made thereunder. The details of conditions under which the licence for the use of Standard Mark may be granted to manufacturers or producers may be obtained from the Bureau of Indian Standards.**

## **6. SAMPLING**

**6.1** Representative samples of containers shall be drawn and their criteria for conformity shall be determined in accordance with the procedure prescribed in Appendix A.

# **A P P E N D I X    A**

## **( Clause 6.1 )**

### **SAMPLING OF PHARMACEUTICAL GLASS CONTAINERS**

#### **A-1. SCALE OF SAMPLING**

**A-1.1 Lot** -- In any consignment all the containers of the same type and nominal capacity belonging to the same batch of manufacture shall be grouped together to constitute a lot.

**A-1.2** Samples shall be tested from each lot for ascertaining the conformity of the containers in the lot to the requirements of this specification.

**A-1.3 Sample Containers** - **When** the lot contains 153 containers or more, 153 containers shall be selected at random from the lot. These 153 containers shall be considered as the sample containers. When, however, the lot contains less than 153 containers all the containers in the lot shall be considered as the sample containers.

**A-1.3.1** In order to ensure randomness of selection, random number tables shall be used. In case such tables are not available, the following procedure is recommended:

Starting from any container in the lot, count them 1,2,3.....up to  $r$  and so on. Every  $r$ th container thus counted shall be chosen,  $r$  being the integral part of  $N/n$ , where  $N$  is the total number of containers in the lot and  $n$  the number of containers to be selected.

## **A-2. NUMBER OF TESTS AND CRITERIA FOR CONFORMITY**

**A-2.1** Take two of the sample containers and test them for alkalinity test (see 4.6) according to the method given in IS:2303-1963\*. If one or both the containers fail the test, the lot shall be rejected without further testing. If both the containers pass the test the remaining sample containers shall undergo further testing.

**A-2.2** From the remaining sample containers, 10 containers shall be selected and tested for thermal endurance (see 4.7). If the number of containers failing the thermal endurance test is two or more, the lot shall be rejected without further testing. If the number of containers failing the thermal endurance test is one or nil, further tests shall be carried out on the remaining sample containers including those which passed the thermal endurance test.

**A-2.3 Requirements Other than Alkalinity and Thermal Endurance** — A sample container failing in one or more of these requirements shall be called a defective.

**A-2.3.1** If the sample containers available for examination regarding these requirements are less than 30, all of them shall be tested for these requirements and no defective shall be permitted.

**A-2.3.2** If they are between 31 and 149, all of them shall be tested for these requirements and only one defective shall be permitted.

**A-2.3.3** In case they are 150 or more, the examination shall be done in stages as given in Table 3.

**A-2.3.4 Stage 1** - In the first stage take 30 sample containers at random. Each of these 30 containers shall be tested for these requirements. If the number of defectives is found to be equal or exceed the rejection number corresponding to the first stage in Table 3 ( that is 4 ), reject the lot without further testing; otherwise proceed to the second stage.

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\*Method of grading glass for alkalinity.

**TABLE 3 CRITERIA FOR CONFORMITY AT DIFFERENT STAGES IN TESTING FOR REQUIREMENTS OTHER THAN ALKALINITY AND THERMAL ENDURANCE TEST**

( Clause A-2.3.3 )

STAGE	SAMPLE SIZE	CUMULATIVE SAMPLE		
		Size	Acceptanc Number	Rejection Number
(1)	(2)	(3)	(4)	(5)
First	30	30	0	4
Second	30	60	3	7
Third	30	90	6	9
Fourth	30	120	8	10
Fifth	30	150	10	11

*A-2.3.5 Stage 2* -In the second stage take another 30 containers at random from the sample containers. Test them for these requirements and add the number of defectives to those found previously. If the total number of defectives in the cumulative sample ( 30 of the first stage + 30 of the second stage, that is 60) is found to be equal to *or less* than the corresponding acceptance number given in Table 3 ( which is three for the second stage), accept the lot; if it is equal to or greater than the corresponding rejection number given in Table 3 ( which is seven for the second stage), reject the lot; if it is between the acceptance number and the rejection number, proceed to the third stage.

*A-2.3.6 Stages 3 to 5* -The procedure for the third and subsequent stages, if any, shall be the same as for the second stage till decision to accept or reject the lot is reached.

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